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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,449	01/12/2004	Steve Dunfield	200208788-1	2134

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EXAMINER	
LEWIS, KIANDRA CHARLE	
ART UNIT	**PAPER NUMBER**
3772	
MAIL DATE	**DELIVERY MODE**
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,449	DUNFIELD ET AL.	
	Examiner	Art Unit	
	Kiandra C. Lewis	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-23 and 46-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-23 and 46-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/2004 5/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1 method claims 1-23 in the reply filed on 4/11/2007 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed 1/12/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. US 6,810,873.

5. As to claims 1, Haikarainen et al. discloses a method for dispensing one or more medicament (col. 2, lines 20-21) comprising: providing a treatment plan having at least two rates of action for one or more medicaments (col. 2, lines 24-26); selecting a droplet characteristic corresponding to each of the at least two rates of action (col. 2, lines 29-

31); and ejecting medicament droplets having each droplet characteristic into a respiratory system of a subject according to the treatment plan, thereby allowing the one or more medicaments to act at two or more rates (col. 2, lines 33-39).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-5, 10-12 16, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haikarainen et al. in view of Coffee US 5,915,377.

10. As to claims 2, 9, 10 and 16, Haikarainen et al, discloses the limitations of the base claim but does not expressly state the step of selecting a droplet characteristic wherein ejecting the medicament droplets each have a droplet size. Coffee however teaches the uses of droplet sprays and teaches that it is known in the art to use dispensing devices that produce divided spray of liquid droplets (col. 1, lines 17-18). It would have been obvious to one having ordinary skill in the art at the time of the invention that if there are two separate chambers from each medicament to be released from as taught by Haikarainen et al. then it would be evident that each droplet is going to have a droplet size comparable to that of the dosing recess ('873, col. 2, lines 29-31). As to claim 3, 47 and 48 it would have been obvious to one having ordinary skill in the art to select the droplet sized based on the predicted change in droplet size for the purpose of effectively treating a patient. It is known in the art that medicament can be delivered for the treatment of any region of the respiratory region whether it be the upper and lower mucosal regions, or oral, nasal, and pulmonary muscosal regions.
As to claim 4, the above combination teaches that there are different orifices of the same medicament ejection apparatus (col. 2, lines 24-29).
As to claim 5, the above combination teaches the use of two different medicaments (col. 2, lines 33-35) each ejected from a different orifices, thus each having the capability of being transferred to the patient via different rates of action.

As to claim 9, it would have been obvious to one having ordinary skill in the art that the site of deposition is going to have an absorption rate corresponding to the rate of action that the droplets are dispersed.

As to claim 11, the above combinations teaches the method in which the two separate medicaments are delivered simultaneously. However it would have been obvious to one having ordinary skill in the art at the time of the invention that the method could be performed by delivering the medicaments simultaneously or not simultaneously for the purpose of modifying treatment to fit a patients needs.

As to claim 12, the above combination teaches ejecting the medicament droplets within the same dose.

11. Claims 6, 7, 13, 14, 17-22, 46, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haikarainen et al. as applied to claim 2-5 above, and further in view of Trueba US 6,684,880.

12. As to claims 6, 7, 13, 14, 46, 49, and 50 the above combinations teaches the method as disclosed in the limitations of claims 2-5, but does not expressly state that the different medicament compositions includes selecting a different concentration of an excipient or that it includes selecting the same bioactive agent for each different medicament composition. Trueba however discloses a means for delivering a composition in which the composition is delivered via ejection of droplets from a dispenser (abstract). Trueba further teaches that the there may be different reservoirs for the storing of the medicament and that the compositition of medicament provided

may be the same or may be of different composition (col. 2, lines 67 – col. 3, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide different concentrations of excipient or similar compositions of bioactive agent for the purpose of effectively treating the illness of the patient and modifying treatment to fit their needs.

As to claim 17, the above combinations teaches a method of dispensing one or more medicaments (col. 2, lines 67 – col. 3, lines 1-8) comprising: selecting a deposition site for respective medicaments on an upper mucosal region and a lower mucosal region of a respiratory system (delivering medicaments to different mucosal regions is known in the art col. 2, lines 44-53; col. 3 lines 27-34) and ejecting medicament droplets of each respective medicament into the respiratory system from the same ejection apparatus (the combinations teaches one apparatus with multiples reservoirs) such that each respective medicament is deposited selectively at its selected deposition site, to enable the respective medicaments to be absorbed at different rates by the selected deposition sites. It would have been obvious to one having ordinary skill in the art at the time of the invention that each region has its own absorption rate thus will inherently absorb the medicament droplets at its own rate of action.

As to claim 18, the above combinations teaches the method in which the two separate medicaments are delivered simultaneously. However it would have been obvious to one having ordinary skill in the art at the time of the invention that the method could be performed by delivering the medicaments simultaneously or not simultaneously for the purpose of modifying treatment to fit a patients needs.

As to claims 19 and 20, the above combination teaches that selecting a deposition site, includes selecting a deposition site on an oral mucosal region and a pulmonary mucosal region (col. 3, lines 27-33).

As to claim 21 and 22, the above combination teaches that the droplet size may be different ('873, col. 2, lines 29-31). Furthermore the art teaches a method of delivering medicament to an oral, nasal and/or pulmonary mucosa ('880, col. 3, lines 27-33).

13. Claims 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haikarainen et al. in view of Piskorz US 2003/0103908.

14. As to claim 15 and 23, Haikarainen et al. disclose the limitations of the base claim but does not expressly state that the treatment plan includes treating the addiction of nicotine. However, it has been known in the art to treat nicotine addition by treatment with a medicament delivered via the use of an in inhaler as taught by Piskorz [0007]. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that one of the medicaments used in the treatment may have been one for the purpose of nicotine addiction.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5,497,764; 5,915,377; 5,941,241; 6,435,175; 6,467,476; 6,571,790; 2003/010308; 6,684,880; 6,705,316; 6,725,860; 6,830,046; 6,883,516; 7,198,044.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCL

4-28-07

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